

### **REMARKS**

Claims 1-2, 4-7 and 10-12 are pending. Claims 3 and 8-9 are canceled. Claim 12 and is new. Claims 1-2 and 10-11 are amended. Support for these amendments and new claims may be found throughout the Specification as filed.

#### Outstanding Issues:

- The Specification is objected to for not providing adequate explanation of the contents of Figures 8A and 11; typographical errors, and trademark usage.
- Claims 1-11 are rejected under 35 U.S.C. 112 ¶ 2 as indefinite.
- Claims 1-11 are rejected under 35 U.S.C. 112 ¶ 1 as lacking adequate written description to support the claims.
- Claims 1-10 are rejected under 35 U.S.C. 102(a) as anticipated by Murata (J. Nara Med. Assoc., V53(No. 5-6), December 2002).
- Claim 11 is rejected under 35 U.S.C. 102(b) as anticipated by WO03/068249 A1.
- Claims 1-11 are rejected under 35 U.S.C. 103(a) as unpatentable over Murata in view of WO03/068249 A1.

#### **I. Corrections to the Specification**

Applicant has amended the Specification to capitalize SUPERDEX® and provide a generic description of these well known gel filtration media. The description of Figure 11 at [0038] now includes the explanation of the arrow previously found in [0124]. The description of Figure 8A at [0033] now identifies the arrows and bar in the figure, as also described at [0044] and [0104] – [0105]. Applicant thanks the Examiner for directing the Applicant's attention to these matters.

**II.** Claims 1-11 are rejected under 35 U.S.C. 112 ¶ 2 as indefinite.

Claim 1 has been amended to clarify that the component is part of a proteoglycan composition. Claim 9 has been canceled. Applicant thanks the Examiner for the Examiner's assistance in improving the clarity of the claims. Applicant respectfully requests the rejection be removed in view of the above clarifying amendments.

**III.** Claims 1-11 are rejected under 35 U.S.C. 112 1 as lacking adequate written description to support the claims.

The Examiner stated that the method steps of claim 11 are adequately described. Applicant has rewritten method claim 11 to remove the prior reference to "the proteoglycan of any one of Claims 1 to 7." Applicant respectfully requests the rejection be removed with regard to claim 11 as amended. Applicant has added product by process claim 12. Based on the adequate description for claim 11, claim 12 is also adequately described (REVISED INTERIM WRITTEN DESCRIPTION GUIDELINES, Example 10).

Claim 1 is rejected as lacking adequate written support. The *per se* requirement recited in the rejection for a sequence listing for the main component is contrary to the law. *Falkner v. Inglis*, 448 F.3d 1357, 1365-68 (Fed. Cir. 2006). However, the claim has been rewritten for clarity, including positively reciting the source material as a limitation. The question under the Written Description standard is whether one of skill in the art would conclude that the inventors possessed the claimed subject matter. Applicant contends that, as now claimed, the proteoglycan composition is fully described by the Specification.

Applicant respectfully requests the rejection be removed in view of the above clarifying amendments.

**IV.** Claims 1-10 are rejected under 35 U.S.C. 102(a) as anticipated by Murata (J. Nara Med. Assoc., V53(No. 5-6), December 2002).

The pending rejection refused allowance of claim 1 as filed because the claimed composition was alleged to be indistinguishable from the crude extract disclosed by Murata, at least within the patent office's ability to discern from the art of record. Applicant has

amended the claims to further define the claimed compositions. The main component of the claimed composition has a molecular weight of 500 kDa or greater and several other recited biophysical characteristics. This is compared to the crude shark cartilage extract of Murata which is a complex heterogeneous mix of proteins (See, *e.g.* Fig. 6 and Fig. 8A). The Applicant has thus disclosed and claimed sufficient biophysical characteristics for the main component to distinguish it over the crude water extracts described in Murata. The prior art composition therefore does not anticipate the pending claims. Applicant respectfully requests the rejection be removed.

**V.** Claim 11 is rejected under 35 U.S.C. 102(b) as anticipated by WO03/068249 A1.

WO03/068249 A1 is available as a 102(b) a printed publication based on its publication date of 21 August 2003. WO03/068249 A1 is thus effective as a printed publication against applications with priority dates on or after 21 August 2004. Applicant's priority date is earlier. Applicant respectfully requests the rejection be removed.

**VI.** Claims 1-11 are rejected under 35 U.S.C. 103(a) as unpatentable over Murata in view of WO03/068249 A1.

WO03/068249 A1 is not available as a 102(b) reference and Murata is distinguished by the claim amendments and arguments above. Applicant respectfully requests the derivative 103(a) rejection be removed.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Application No. 10/574,400  
Amendment dated  
Reply to Office Action of November 14, 2006

Docket No.: HO-P03167US0

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-2375, under Order No. HO-P03167US0 from which the undersigned is authorized to draw.

Dated: 14 March 2007

Respectfully submitted,

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